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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/109,858	07/02/1998	MAHENDRA S RAO	T5530.CIP	4010
7590 10/14/2003			EXAMINER	
JANE MASSEY LICATA, ESQ LAW OFFICE OF JANE MASSEY LICATA 66 E. MAIN STREET			HAYES, ROBERT CLINTON	
			ART UNIT	PAPER NUMBER
MARLTON, NJ 08053			1647	hr
			DATE MAILED: 10/14/2003	36

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/109,858

Applicant(s)

Rao et al

Examiner

Robert C. Hayes, Ph.D.

Art Unit 1647



-- The MAILING DATE of this communication appears on the cover she t with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filled after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) X Responsive to communication(s) filed on *May 27, 2003* 2b)  $\square$  This action is non-final. 2a) X This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims 4) X Claim(s) 12, 15, 16, 21, 24, 26, 27, and 60 is/are pending in the application. 4a) Of the above, claim(s) \_\_\_\_\_\_\_ is/are withdrawn from consideration. 5) 💢 Claim(s) <u>12, 15, 16, 21, 24, 26, and 27</u> is/are allowed. 6) X Claim(s) 60 is/are rejected. 7) Claim(s) \_\_\_\_\_\_\_ is/are objected to. are subject to restriction and/or election requirement. 8) Claims **Application Papers** 9) Light The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11). The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some\* c) ☐ None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \*See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). a) The translation of the foreign language provisional application has been received. 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 5) Notice of Informal Patent Application (PTO-152) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 33 6) Other:

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## **DETAILED ACTION**

## Response to Amendment

- 1. The amendment filed 5/27/03 has been entered.
- 2. The rejection of claim 59 under 35 U.S.C. 112, second paragraph, for omitting essential steps is withdrawn due to the cancellation of this claim.
- 3. The rejection of claims 12, 15-16, 21, 24, 26-33 & 59 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitations of "adherent growth supporting medium", "retinoic acid containing medium", "astrocyte-promoting medium", "feeder-cell-independent culture", "proliferating conditions" and "differentiating conditions" are withdrawn either due to the amendment of the claims, cancellation of the claims, or due to Applicants' arguments.
- 4. The rejection of claims 15 & 16 under 35 U.S.C. 112, second paragraph, for lack of proper antecedent basis is withdrawn due to the amendment of the claims.
- 5. The rejection of claims 26-27 under 35 U.S.C. 102(b) as being anticipated by Blass-Kampmann et al. (1994) is withdrawn due Applicants' arguments related to a "pure" population of rodent CNS neuron-restricted precursor cells not being taught by Blass-Kampmann et al. See Abstract.

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- 6. The rejection of claims 26-28, 29 & 32-33 under 35 U.S.C. 102(e) as being anticipated by Boss et al. (U.S. Patent 5, 5,411,883) is withdrawn due to the cancellation of the claims, or due to Applicants' arguments.
- 7. Applicant's arguments filed 5/27/03 has been fully considered but not deemed to be persuasive.
- 8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 9. New claim 60 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the instant specification at the time of filing the instant application is apparent for using "mammalian" embryonic stem cells. In contrast, only use of mouse ES cells were contemplated on pages 20 and 55 of the specification; thereby, constituting new matter for the different scope now claimed.

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New claim 60 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for similar reasons made of record for cancelled claim 59, for the similar reasons made of record in Paper NOs: 5 (mailed 10/5/99), 10 (mailed 5/24/00) & 17 (mailed 1/31/01) & 32 (1/24/03) for now obtaining and using "mammalian" stem (ES) cells.

Applicants' arguments regarding the effective priority date should be 7/2/98, as it relates to ES cells is correct. However, even in this CIP application, only use of mouse ES cells were contemplated on pages 20 and 55 of the specification. Therefore, Applicants did not adequately describe use of the genus of "mammalian" ES cells, similar to that previously made of record for "human" ES cells. Moreover, in that neither Thompson (1995), (1996), (1997) nor (1998) have been made of record in the instant application in a properly executed IDS, nor copies provided to the Examiner, no comment from the Examiner is currently feasible. It is further noted that reference to Carpenter et al (2001) or Mayer-Proschel et al (2002) is irrelevant to the instant rejection; especially in light of these references being 3 and 4 years, respectively, after the priority of the instant application, which is consistent with that held by the court in *In re* Hogan and Banks previously made of record.

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11. Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unknown what metes and bounds exactly constitutes "neural differentiating conditions", which confuses what exactly is envisioned as the required medium to practice the invention.

- 12. Claims 12, 15, 16, 21, 24, 26 & 27 are allowed.
- 13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.

October 7, 2003

GARY KUNZ

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600